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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,988	07/13/2005	Rainer Kraft	2002.738US	4277
7590 03/12/2007				
F Aaron Dubberly		EXAMINER		
Akzo Nobel Inc		FAYYAZ, NASHMIYA SAQIB		
Intellectual Property Department				
7 Livingstone Avenue		ART UNIT PAPER NUMBER		
Dobbs Ferry, NY 10522-3408		2856		
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE		DELIVERY MODE
3 MONTHS		03/12/2007		PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/538,988

Applicant(s)

KRAFT, RAINER

Examiner

Nashmiya S. Fayyaz

Art Unit

2856

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 12-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19 is/are allowed.
- 6) ☒ Claim(s) 12-18,20 and 21 is/are rejected..
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 9/6/05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 12-18, 20 and 21 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 12, it is unclear if the combination of a vessel and a sampling tube are being claimed or just the vessel with the intended usage of a sampling tube. Claim 20 depends from claim 1 which is cancelled. Also, it does not appear to further limit the "vessel" being claimed in claim 12. As to claim 18, it refers to a method of claim 15 where claim 15 is drawn to the vessel. Further, these steps do not seem to further limit claim 15.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 12-16, 18 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sinnreich et al- US Patent # 5,827,984. As to claim 12, Sinnreich et al disclose a device for simulation of dissolution of pharmaceutical dosage including an inert vessel wall and bottom (beaker 21 with floor 211) with fluid medium P, inert retainer (glass base 26) for retaining the pharmaceutical device (dosage D) and providing a passageway to the bottom (through openings 261), see fig. 3 and col. 6 lines 20 et seq. Further, it is noted that Sinnreich et al lack a teaching for the intended usage of passing a sample tube through the passageway. However, it is noted that in the Sinnreich et al device, a sample tube *is capable of* being passed through the openings 261 such that it would have been obvious to one of ordinary skill in the art at the time of the invention to have collected a sample by passing the sample tube through the openings 261 depending upon where it is desired to collect the sample. As to claim 13, the vessel is beaker and appears to be made of glass. As to claim 14, base appears to be a plate with annular openings near the middle. As to claim 15, it appears the plate (base 26) is fixed to feet 262. As to claim 16, the retainer consists of a ledge "protruding inwardly" from the vessel bottom. As to claim 20, as best understood, note col. 9, lines 19-35 which indicates providing plural bases 26 and containers 21 and agitating devices 23 and obviously plural sampling tubes 7. As to claim 21, note refilling tubes 8.

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5. Claims 12<sup>13, 20 and 21</sup> are rejected under 35 U.S.C. 103(a) as being unpatentable over Barnwell et al- WO 96/28717. As to claim 12, Barnwell et al disclose a testing vessel including vessel 1 with walls and a bottom with medium 3 and retainer 6 which is a mesh or screen with passageways or openings, see fig. It is noted that Barnwell lacks a teaching for opening in the mesh are intended for a sampling tube or that the material is inert. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to have realized that the openings in the screen/mesh are capable of providing the intended usage of sampling and that mesh material would have to be inert so as to avoid interference with the testing of the solution. As to claim 13, usage of glass is old and well-known in the art of dissolution testing. As to claim 14, insert 6 appears to be in the form of a plate at the vessel wall. As to claim 15, shoulder 5 is part of the retainer which is permanently part of the vessel wall and constitutes 2 bulges of claims 16 and 17. As to claims 20 and 21, as best understood, official notice is taken that provision of plural vessels with stirring means, sampling and refilling is old and well-known in the art of dissolution testing such that it would have been obvious to one of ordinary skill in the art at the time of the invention to have performed duplication of parts for simultaneous testing of multiple samples.

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***Allowable Subject Matter***

6. Claim 19 is allowed.

7. The following is a statement of reasons for the indication of allowable subject matter: the primary reason for allowance of claim 19 is that the prior art fails to teach or suggest a method for dissolution testing of an annular device comprising placing a fluid medium and stirring means in a dissolution vessel comprising an inert retainer provided by or at the vessel wall or vessel bottom...along with providing a passageway to the vessel bottom for a sampling tube;... placing the annular delivery device in the retainer; along with inserting a sampling tube through the passageway; and sampling one or more predetermined volumes of the fluid medium at selected time intervals by means of the sampling tube.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashmiya S. Fayyaz whose telephone number is 571-272-2192. The examiner can normally be reached on Mondays and Thursdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron E. Williams can be reached on 571-272-2208. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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Art Unit 2856

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